TESTIMONY PRESENTED BEFORE THE PUBLIC HEALTH COMMITTEE

March 7, 2012

House Bill #5335 -- AN *ACT CONCERNING LYME DISEASE TESTING*

Respectfully Submitted By: **Marie L. Benedetto**

Issue: Is Lyme Disease Testing in the State of CT reliable, diagnostically significant, and comprehensive enough for results to be generally accepted and subsequently appropriately treated for the disease/related co-infections?

Conclusion: No (based on the information provided below)

Recommendation: CT Task Force to broaden its initially indicated role (as described in House Bill #5335) to include (not only testing) but other areas such as (similarly to the ***Virginia Governor's Task Force on Lyme Disease*** http://www.nap.edu/catalog.php?record_id=13134#toc (see Virginia final report):

- Diagnosis
- Treatment
- Prevention
- Impact on Children
- Public Education/Awareness
- Animal/Environmental Issues
- Additional Health Risks associated (e.g. blood donors)

Cited problems (widely known and accepted from various resources) **with testing for Lyme Disease** (see Columbia University – Lyme Research Division http://www.columbia-lyme.org/patients/ld_lab_test.html)

Two Tests (antibody) commonly used for Lyme Disease Testing – **ELISA** screening and **Western Blot**:

- Do not necessarily tell whether or not the infection is still present
- Does not reveal if the whether or not infection continues to persist

ELISA (for screening purposes) (quantitative test) Enzyme Linked Immunosorbent Assay Inexpensive and widely used automated screening process – reporting a single number of relative quantities of lyme antibodies in patients serum

- Can result in false negatives and false positives
- Sensitivity of ELISA vary considerably from (estimated as low as 55%) depending upon clinical manifestations and duration of infection

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Western Blot – (qualitative test) measures antibodies to specific strains (outer protein specific)

- Interpretation requires considerable skill at the lab level (lab expert reading visual bands present or absent)
- Interpretation requires considerable knowledge at the physician level
- Use of "lab created" antigens – invitro vs. invivo Researchers have found that there are antigens expressed in vivo and others expressed in vitro. *Therefore, the assays that are used to identify antibodies need to include those antigens expressed in vivo*. Per **Critical Needs and Gaps in Understanding Prevention, Amelioration, and Resolution of Lyme and Other Tick-Borne Diseases-The Short-Term and Long-Term Outcomes: Workshop Report**
  http://www.nap.edu/catalog.php?record_id=13134#toc

- US CDC advocates 2/3 bands for IgM and 5/10 bands for IgG to provide uniformity however:
  - Specific bands such as 31kD (outer surface protein A) and 34kD (outer surface protein B) band are currently missing from the testing. These are the same proteins that were used to make the human vaccine for Lyme Disease (LYMErix, was developed by GlaxoSmithKline. LYMErix was approved on the basis of these trials by the U.S. Food and Drug Administration (FDA) on December 21, 1998 – later pulled off the market due to claims of autoimmune disorders on patients who received the immunization).
  - Borrelia burgdorferi (lyme spirochete bacteria) is known to have other strains not included in any testing, but found incidence in the tick populations.

- Co-Infections (specifically Babesia (a parasite that behaves similarly to malaria) and Bartonella (cat scratch fever bacteria) can exacerbate the "Lyme" symptoms, turning off the body's natural immune system and inhibiting the body to fight the infection of the bacteria. When this happens, no antibodies to the Lyme Bacteria are produced and therefore, no opportunity to ever test "positive" in the above testing scenarios, yet still be very ill.

For more information on incidence of co –infections: http://www.columbia-lyme.org/research/documents/NotzonCoinfectionpaper.pdf

Testing for Lyme Disease can be a complicated and uncertain process, potentially leading to misdiagnosis, inaccurate reporting and surveillance, and therefore, inappropriate treatment and misguided public awareness.

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Variables to consider when evaluating a (tick borne illness) lyme/co-infection testing protocol might include:

- Did the person know if they were bitten by a tick (nymph ticks can be smaller than a head of a pin)? If not, maybe a list of questions/protocol from physician to patient indicating symptoms, timing, risk of tick bites, etc. (How well-recognized are Lyme/co-infection symptoms by general practioners/pediatric doctors?) See checklist – Dr. Burrascano 2008 Diagnosis & Treatment Guidelines – pages 9-11
  http://www.lymenet.org/BurrGuide200810.pdf

- If the tick can be recovered from the bite, is the tick infected or not? Should it be sent for testing?

- Is it just deer ticks or can other ticks transmit the disease?

- What is the time difference between tick bite and lab test (current literature indicates testing may not detect antibodies if enough time has not elapsed for the antibodies to be produced in sufficient detectable quantities)?

- Common protocol (Infectious Disease Society of America) starts with ELISA. Is ELISA sensitive enough to be of value when some sensitivity can be as low as 55%?

- Common protocol, if ELISA is positive, is the Western Blot:
  - Which laboratory will be used and what procedures will the laboratory use?
  - Which bands will be tested?
  - What values for each band are considered significant?
  - Against what standard are results interpreted?

- Another protocol includes PCR (polymerase chain reaction). Does the Lyme bacteria exist in the specific part of the body from which fluid is drawn for the PCR test or is the bacteria resident in another part of the body?

- Does the testing include other tick-borne diseases such as Babesia, Ehrlichia and Bartonella?

- Does the patient live in an endemic area?

- Are commonly used tests appropriately used for diagnosis or were they intended for surveillance only?

- Are serologic tests specific enough, sensitive enough and definitive enough to rule out Lyme Disease if the tests are negative?

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- Are serologic tests sufficient to diagnose an individual without clinical considerations?
- Are serologic tests able to distinguish between antibodies from a current infection vs. that of a past infection?
- Should the test results indicate sensitivity (reliability) and clinical significance? Should the specifically acknowledge that a negative result may not preclude incidence of the bacteria/other?

Personal Experience: Lyme/co-infected daughter, undiagnosed for 6 years (Age 5 to current age 12)

Symptoms: Chronic fatigue/stamina issues, night sweats, vision, hearing issues, cognitive/fogginess issues, lower body temperature, sleep issues, continued illness, walking/balance issues, food sensitivities, compromised immune system, fevers, neurological dysfunction/weakness on right side of body, excruciating burning shooting pains, paralysis of leg – arm- face, temporary blindness, numbness, memory loss, at times unable to walk or talk, unable to attend her fourth-grade year at school….

Treatment from medical community – passive, not knowledgeable, unwilling to link symptoms holistically, general disregard, implied mental illness, even with knowledge of tick bite and risk factors.

Finally received treatment with antibiotics (oral and IV) and holistically treated to support immune, endocrine, and nervous system. She is currently doing well in school, has more stamina, better concentration, stronger immune system. Unfortunately due to the prolonged disease, some permanent damage may have been done (thyroid and nerve damage) and will continue to have to be monitored for relapses (due to how the bacteria can hide and wait for an opportunity) and then will be treated. She is left with memories of her childhood being ill, in pain/incapacitated at times.

With better public/medical awareness, better testing/clinical symptoms acceptance, we can do better to help people more timely.

I challenge you, our state legislators, to come together and find common ground on widely accepted knowledge of symptoms, testing/risks, and general overall health of our citizens (young and old).

Please help us and the future legislators of our state – our children.